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TECHNIQUE

Primary transcatheter umbrella closure of perimembranous ventricular septal defect

Michael L Rigby, Andrew N Redington

Abstract

***Objectives*—The starting hypothesis was that some perimembranous ventricular septal defects can be closed safely and effectively with a Bard Rashkind double umbrella introduced through a long transvenous sheath.**

***Design*—A descriptive study of all patients who underwent attempted transcatheter umbrella closure of a perimembranous ventricular septal defect. Those patients selected for the study had symptoms of a ventricular septal defect and a perimembranous ventricular septal defect shown by transthoracic echocardiography. The morphological criteria used were a posterior perimembranous defect with a diameter of $\leqslant$ 8 mm not associated with overriding of the aortic or pulmonary valve or with aortic valve prolapse. The haemodynamic criteria for inclusion in the study were a right to left ventricular systolic pressure ratio of > 0·45, a Doppler derived right ventricular systolic pressure of > 50 mm Hg, and a pulmonary to systemic flow ratio > 3:1.**

***Setting*—A tertiary referral centre.**

***Patients*—13 infants, children, and adolescents with a perimembranous ventricular septal defect aged 3 weeks to 16 years and weighing 1·8–46 kg.**

***Interventions*—A modified Rashkind ductal double umbrella was introduced through a long transvenous sheath and positioned on either side of the ventricular septal defect. Placement was guided by transoesophageal echocardiography.**

***Results*—10 out of 13 patients underwent successful partial or complete closure of a perimembranous ventricular septal defect. There were three placement failures. Two of these were associated with a ventricular septal defect too large for the umbrella device. In a third case the umbrella was opened in the left ventricular outflow tract necessitating surgical removal and closure of the ventricular septal defect.**

***Conclusion*—Transcatheter umbrella closure of a perimembranous ventricular septal defect is technically feasible and can be therapeutically successful, although the procedure is moderately difficult to perform and the mean procedure time is > 120 minutes. It is an alternative to surgery in some cases, but the overall results would not support its routine use even with the introduction of larger devices of the current design.**

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Department of Paediatric Cardiology, Royal Brompton Hospital, London
M L Rigby
A N Redington

Correspondence to:
Dr M L Rigby, Department of Paediatric Cardiology, Royal Brompton Hospital, Sydney Street, London SW3 6NP.

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The Rashkind double umbrella, originally designed for closure of a persistent arterial duct,[1] has subsequently been used for the transcatheter closure of numerous other extracardiac and intracardiac communications.[2] The device has been used for the closure of ischaemic ventricular septal defects, muscular defects, and iatrogenic ventricular septal defects occurring after cardiac surgery.[3 4] The Lock clamshell device that was designed specifically for closure of secundum atrial septal defects[5] has also been used to successfully occlude muscular ventricular septal defects and residual septal defects after cardiac surgery[6] and interatrial communications after the fenestrated Fontan procedure.[7] It is not now available for clinical use. The hypothesis that we set out to test was that some perimembranous defects could be closed safely and effectively by a Bard Rashkind ductal umbrella.

There have been no descriptions of the use of an umbrella device for the closure of perimembranous ventricular septal defects. There are several possible reasons for this. Firstly the results of conventional surgery are excellent and an operative mortality approaching zero can be anticipated. Secondly most perimembranous ventricular septal defects that need closure will occur in patients under the age of 12 months in whom the ventricular septal defect is too large for closure with the Rashkind ductal umbrella with its maximum diameter of 17 mm permitting closure of defects of up to only 8 mm. Thirdly all perimembranous ventricular septal defects by definition are close to the aortic and tricuspid valves[8] so that any attempt at umbrella closure could theoretically give rise to considerable distortion of both the aortic and tricuspid valves. Finally the shape and design of the Rashkind umbrella is not ideal for closure of a ventricular septal defect because close apposition of the arms of the device with the ventricular septum is not

readily achieved. We have previously described, however, our modification of the Rashkind ductal umbrella, and its use to treat a variety of different intracardiac and extracardiac communications.[2] The modification permits better apposition of the umbrella arms with the septum. In this study we review our total experience of its use in the closure of perimembranous ventricular septal defects.

Patients and methods

Since October 1990, 13 infants, children, and adolescents have undergone attempted transcatheter umbrella closure of a perimembranous ventricular septal defect with a modified Bard Rashkind ductal umbrella.

Patients were selected according to a previously agreed protocol with full and informed consent. In keeping with the protocol patients admitted to the study had a perimembranous ventricular septal defect and had symptoms that could be attributed to the defect. There was no upper or lower body weight or age. Prospective patients for inclusion in the study each underwent transthoracic echocardiography and satisfied a number of rigid criteria before being included.

Any patients with important malalignment of the outlet septum, with overriding of the aorta or pulmonary trunk, with fibrous continuity between the aortic and pulmonary valves, or with aortic valve prolapse were excluded. The smallest diameter of the ventricular septal defect was 8·5 mm. To be considered for inclusion the Doppler derived right ventricular systolic pressure, calculated from the arm blood pressure and peak instantaneous systolic gradient across the ventricular septal defect, had to be at least 50 mm Hg in the absence of any pulmonary stenosis.

Patients who up to this point had satisfied the criteria for entry into the study then underwent cardiac catheterisation and angiography under general anaesthesia and 11 patients had transoesophageal echocardiography. A Hewlett Packard paediatric mini probe (for patients < 15 kg) or adult probe interfaced with an HP Sonos 1500 ultrasound scanner was used. The right and left heart was catheterised with selective left ventriculography. To be chosen for umbrella closure of the defect the pulmonary to systemic flow ratio had to be > 3:1, the right to left ventricular systolic pressure ratio > 0·45, and transoesophageal echocardiographic measurement of the smallest diameter of the ventricular septal defect < 8·5 mm.

Umbrella closure of the ventricular septal defect was attempted at the time of cardiac catheterisation, with the umbrella modified according to the method previously described.[2] A size 5French (F) end hole catheter was introduced into the left ventricle from the femoral vein and exchanged for an appropriately sized long transeptal sheath. In one patient it was not possible to enter the left ventricle directly from the right ventricle. Accordingly a retrograde arterial end hole catheter was passed from the left ventricle to the right ventricle and then to the pulmonary artery. The catheter was replaced with an exchange guide wire that was snared through a right heart catheter and pulled to the femoral vein. Thus a long wire formed a loop from the femoral vein, through the ventricular septal defect to the femoral artery. A transeptal sheath was then advanced over the wire from the femoral vein to the left ventricle. For defects < 6 mm minimal diameter, a 12 mm modified ductal umbrella was used and introduced through a 6 F or 8 F sheath. For larger defects a 17 mm modified ductal umbrella was introduced through an 8 F, 9 F or 11 F sheath. The umbrella was loaded and positioned with either the standard technique developed for closure of an arterial duct[1] (seven patients) or front loaded into a smaller sheath according to the method of Perry and Lock (six patients).[9] The final positioning of the device was dependent on transoesophageal echocardiographic screening (11 patients) used simultaneously with standard radiographic screening. Final release of the umbrella device was performed only when the position seemed satisfactory and aortic or tricuspid insufficiency had been excluded by transoesophageal echocardiography with colour flow Doppler.

Results

Thirteen infants, children, and adolescents were entered into the study. Their weights ranged from 1·8 to 46 kg. There were six patients under the age of 1 year and five between 1 and 5 years. The two oldest patients were 10 and 16 years.

The procedure time ranged from 75 to 220 (mean 122) minutes and the radiographic screening time from (mean 32) 15 to 46 minutes. A 12 mm ductal umbrella was used in the three smallest infants, in the rest a 17 mm device was used. During the procedure the two smallest infants (1·8 and 2·2 kg) developed transient complete heart block, lasting four days in one.

The immediate results were successful placement of an umbrella in 10 (figs 1 and 2), embolisation of the device to the pulmonary artery with immediate transcatheter retrieval in one, and faulty positioning of the umbrella in the left ventricular outflow tract in one. This patient (weight 2·2 kg) underwent surgical retrieval of the umbrella and closure of the ventricular septal defect but died of sudden and refractory asystole during the early postoperative period. In one patient there was an apparently successful placement of the umbrella, but embolisation to the aorta occurred four hours later. Transcatheter retrieval was uneventful.

The immediate haemodynamic effects of successful placement of the umbrella were a reduction in the mean right to left ventricular systolic pressure ratio from 0·72 to 0·40 and a fall in the mean pulmonary to systemic flow ratio from 4·2:1 to 2·2:1. Transthoracic echocardiography performed 24 hours after the procedure showed that only two patients

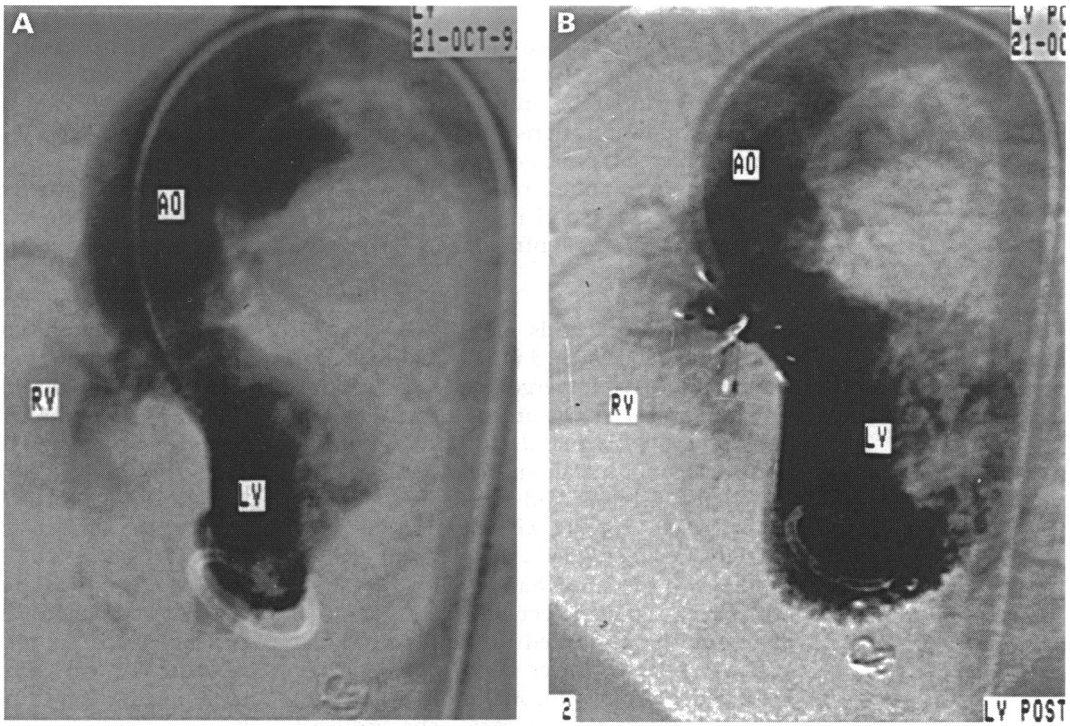

Figure 1 Left ventriculography showing a perimembranous ventricular septal defect (A) before and (B) after umbrella closure. LV, left ventricle; RV, right ventricle; AO, ascending aorta.

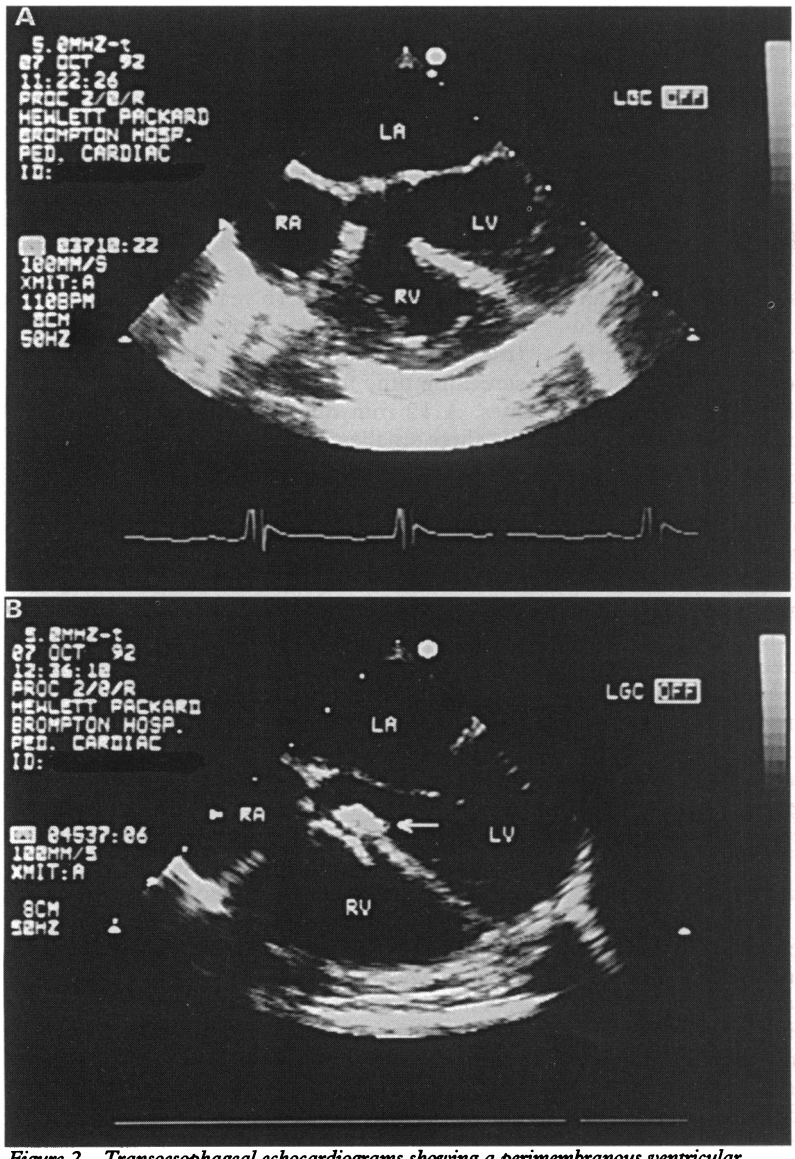

Figure 2 Transoesophageal echocardiograms showing a perimembranous ventricular septal defect (A) before and (B) after umbrella closure. LA, left atrium; RA, right atrium; LV, left ventricle; RV, right ventricle; arrow points to umbrella.

had complete closure of the defect although in the rest there had been a considerable reduction in defect size. Very mild tricuspid regurgitation was present in two and none had aortic regurgitation. Two patients developed prolonged haemolysis subsiding over a period of seven and 12 weeks. No patient developed any vascular complications attributable to the procedure and in each case extubation was performed immediately at the end of the operation. Follow up of the study group has ranged from one to 36 months (mean 17). Complete closure of the ventricular septal defect within 12 months of the procedure was achieved in four patients. Incomplete closure with a small but continuing left to right shunt occurred in five. One patient who underwent the procedure at 3 months (weight 3·6 kg) has a significant continuing left to right shunt 10 months later with recurrent chest infections, a right to left ventricular systolic pressure ratio of 0·5 and moderate aortic incompetence, not present in the immediate follow up period. A 17 mm umbrella had been used. One infant died three months after successful complete closure of a defect but the cause of death was unrelated congenital pulmonary lymphangiectasia. Excluding the one patient with a moderately large residual ventricular septal defect, and the infant who died, the rest are symptom free.

Discussion

Ten out of 13 patients underwent successful partial or complete closure of a perimembranous ventricular septal defect with a modified Rashkind ductal umbrella introduced through a long sheath from the femoral vein. It is self evident from the small number of patients entered into the study during a three year period that with currently available equip-

ment, transcatheter umbrella closure of a ventricular septal defect can be considered only in a few patients.

We have shown, however, that a modified device can be positioned in a perimembranous ventricular septal defect with complete closure of the defect in some and with a considerable reduction in the pulmonary to systemic flow ratio and right to left ventricular systolic pressure ratio in the others. The most important aid to precise placement of the umbrella device was transoesophageal echocardiographic screening. Only two patients developed tricuspid regurgitation. This was mild in both cases. Late aortic insufficiency developed in the only patient with a large residual defect that will need surgical repair. Complete heart block occurred transiently in the two smallest infants. No patient has developed right or left bundle branch block.

Embolisation of the umbrella in two cases was shown to be due to an underestimate of the size of the ventricular septal defect so that the 17 mm device was too small. Malpositioning of the umbrella in the left ventricular outflow tract of the small infant (weight 2·2 kg) was in part a consequence of extreme resistance to passing the 12 mm umbrella through a 6 F long sheath offering poor control at the distal end of the sheath. This was the only case in which front loading of the umbrella resulted in difficulties in placement of the umbrella. Importantly, this infant did not have simultaneous transoesophageal echocardiography. This contributed to difficulties in positioning the umbrella.

A critical appraisal of these results shows that overall they are disappointing when compared with conventional surgery. Residual shunts with continuing risk of endocarditis are common and morbidity from transient heart block, chronic haemolysis, and aortic regurgitation has been encountered. The procedure can be moderately long and similarly the radiographic screening time can be > 40 minutes.

It would seem that umbrella closure of ventricular septal defects with currently available techniques and devices is better applied to some muscular defects and some residual defects present after cardiac surgery. Nevertheless we have shown that complete or partial closure of a perimembranous ventricular septal defect is technically feasible and can be therapeutically successful. Although not applicable to most patients it can be an alternative to conventional surgery in some. It is clear that the overall results would not support the routine use of the Rashkind double umbrella for closure of perimembranous ventricular septal defects even if a larger device of the current design was introduced. It is feasible that further modifications to the basic design could improve the outcome of the technique so that continued evaluation would be justified.

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